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| 10/613,517 | 07/03/2003 | Dirk Boecker | 38187-2688.US | 4774 |
| 77845 | 7590 | 06/16/2009 | EXAMINER | |
| Goodwin Procter LLP | | | HOEKSTRA, JEFFREY GERBEN | |
| Attn: Patent Administrator | | | ART UNIT | PAPER NUMBER |
| 135 Commonwealth Drive | | | 3736 | |
| Menlo Park, CA 94025-1105 | | | | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/613,517 | BOECKER ET AL. |
| | Examiner | Art Unit |
| | Jeffrey G. Hoekstra | 3736 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 April 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,13-17,21,24,27,52,54,57 and 65 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,13-17,21,24,27,52,54,57 and 65 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 03 May 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/9/04, 12/21/04, 3/14/07, 3/23/07, 5/6/08, 8/4/08, 9/30/08, and 11/20/08.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 04/14/2009, amended claim(s) 1, 54, and 65 and canceled claim(s) 2-12, 18-20, 22-23, 25-26, 28-51, 53, 55-56, 58-64, and 66-67 is/are acknowledged. The following is/are set forth:

Election/Restrictions

2. Applicant's election of Species B2, A3, B4, A5, A6, B7, and B8 in the reply filed on 04/14/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 2-6, 8-12, 18-20, 22-23, 25-26, 28-51, 53, 55-56, 58-64, and 66-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/14/2009.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

6. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

7. The disclosure of the prior-filed application, Application No. 10/425,815, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 10/425,815 is not only not commonly assigned but it is also not concerned with sampling and sensing analytes in a bodily fluid.

Information Disclosure Statement

8. The information disclosure statement(s) (IDS) submitted on 2/9/04, 12/21/04, 3/14/07, 3/23/07, 5/6/08, 8/4/08, 9/30/08, and 11/20/08 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

9. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Specification

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

11. Claim 13 is objected to because of the following informalities: the positive recitation of "a penetrating member" in lines 2 and 4 should apparently read "the active one of said penetrating members". Appropriate correction is required.

12. Claim 21 is objected to because of the following informalities: the positive recitation of "the driver" in line 1 should apparently read "the penetrating member driver". Appropriate correction is required.

13. Claim 24 is objected to because of the following informalities: the positive recitation of “a penetrating member” in line 2 should apparently read “the active one of said penetrating members”. Appropriate correction is required.

14. Claim 27 is objected to because of the following informalities: the positive recitation of “a penetrating member” in line 2 and the positive recitation of “the penetrating member” should apparently read “the active one of said penetrating members”. Appropriate correction is required.

15. Claim 52 is objected to because of the following informalities: the positive recitation of “a target tissue” in line 2 and the positive recitation of “the target tissue” should apparently read “the tissue site”. Appropriate correction is required.

16. Claim 57 is objected to because of the following informalities: the positive recitation of “wherein each penetrating member each penetrating member” in lines 1-2 should apparently read “wherein each of the plurality of penetrating members”. Appropriate correction is required.

17. Claim 65 is objected to because of the following informalities: the positive recitations of “a tissue site” in line 18 should apparently read “the tissue site”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 24, 27, 52, 54, and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20. Claims 24 and 27 depend on cancelled claim 22. Claims 52 and 54 depend on cancelled claim 50. The scope of claims 24, 27, 52, and 54 is indeterminate as being dependent upon a cancelled claim. For the purpose of examination on the merits, each of claims 24, 27, 52, and 54 is being treated as depending from independent claim 1.

21. Claims 24 and 27 recites the limitation "the processor" in line 1. There is insufficient antecedent basis for this limitation in the claim.

22. Claim 52 recites the limitation "the tissue stabilizer device" in line 1. There is insufficient antecedent basis for this limitation in the claim.

23. Claim 54 recites the limitation "at least one of the distal port or proximal port of disposable" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Applicant may have intended to positively recite "at least one of a distal port or a proximal port on the disposable".

24. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: at least "a first fracturable seal". Claim 54 positively recites "a second fracturable seal". The scope of the claim is indeterminate with respect to how a "second fracturable seal" may be disposed on the disposable in the absence of "a first fracturable seal". For the purpose

of examination on the merits, the claim limitation is being treated as positively reciting "a first fracturable seal" consistent with the instant Specification.

25. Claim 65 recites the limitation "said elongate portion of the penetrating member" in line 17. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

27. Claims 1, 24, 52, 54, 57, and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Levaughn et al. (US 7,150,722 B2, hereinafter Levaughn).

28. For claim 1, Levaughn discloses and shows a body fluid sampling system (2) for use on a tissue site (Abstract), the system comprising *inter alia*:

- a disposable (50) (as best seen in Figure 4) (column 14 line 9 – column 16 line 57);

- a penetrating member driver (44) (as best seen in Figure 3) (column 14 line 9 – column 16 line 57);
- a plurality of penetrating members (8) (as best seen in Figure 4) (column 14 line 9 – column 16 line 57) arranged in a radial configuration on the disposable (as best seen in Figure 4) (column 14 line 9 – column 16 line 57), wherein sharpened distal tips of the penetrating members point radially outward (as best seen in Figure 4) (column 14 line 9 – column 16 line 57), wherein an active one of said penetrating members may be operatively coupled to said penetrating member driver (column 14 line 9 – column 16 line 57), said penetrating member driver moving said active one along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site (column 14 line 9 – column 16 line 57); and
- a plurality of analyte detecting members (10) (as best seen in Figure 4) (column 14 line 9 – column 16 line 57), wherein at least one of said analyte detecting members is positioned to receive fluid from a wound created by said active one of said penetrating members (as best seen in Figure 1) (column 14 line 9 – column 16 line 57), wherein said detecting members are not pierced by the active one of the penetrating members (as best seen in Figure 4) (column 14 line 9 – column 16 line 57).

29. For claim 21, Lebaugh discloses and shows a body fluid sampling system, wherein the driver is a motor and gear box (column 14 line 9 – column 16 line 57).

30. For claim 52. (original) The system of claim 50, wherein a tissue stabilizer device (32) (as best seen in Figure 1) (column 14 line 9 – column 16 line 57) is configured to apply a force to a target tissue and cause the target tissue to press in an inward direction relative to the housing member (as best seen in Figure 1) (column 14 line 9 – column 16 line 57) r.

31. For claim 54, Levaughn discloses and shows a body fluid sampling system, further comprising a fracturable seal (86) located at least one of the distal port or proximal port of disposable (as best seen in Figure 3) (column 14 line 9 – column 16 line 57).

32. For claim 57, Levaughn discloses and shows a body fluid sampling system, wherein each penetrating member each penetrating members is an elongate member without molded attachments (as best seen in Figure 4) (column 14 line 9 – column 16 line 57).

33. For claim 65, Levaughn discloses and shows a body fluid sampling system (2) for use on a tissue site (Abstract), the system comprising *inter alia*:

- a disposable (50) (as best seen in Figure 4) (column 14 line 9 – column 16 line 57);
- a penetrating member driver (44) (as best seen in Figure 3) (column 14 line 9 – column 16 line 57);
- a plurality of penetrating members (8) (as best seen in Figure 4) (column 14 line 9 – column 16 line 57) arranged in a radial configuration on the disposable (as best seen in Figure 4) (column 14 line 9 – column 16 line 57), wherein sharpened distal tips of the penetrating members point radially outward (as best seen in Figure 4) (column

14 line 9 – column 16 line 57), wherein an active one of said penetrating members may be operatively coupled to said penetrating member driver (column 14 line 9 – column 16 line 57), said penetrating member driver moving said active one along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site (column 14 line 9 – column 16 line 57);

- a plurality of analyte detecting members (10) (as best seen in Figure 4) (column 14 line 9 – column 16 line 57), wherein at least one of said analyte detecting members is positioned to receive fluid from a wound created by said active one of said penetrating members (as best seen in Figure 4) (column 14 line 9 – column 16 line 57), wherein said detecting members are not pierced by the active one of the penetrating members (as best seen in Figure 1) (column 14 line 9 – column 16 line 57); and
- a coupler (48) (as best seen in Figure 3) (column 14 line 9 – column 16 line 57) on said penetrating member driver configured to engage at least a portion of said elongate portion of the penetrating member and drive said member along a path into a tissue site and withdrawn from a tissue site (as best seen in Figure 3) (column 14 line 9 – column 16 line 57).

Claim Rejections - 35 USC § 103

34. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

36. Claims 13-17, 24, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levaughn et al. (US 7,150,722 B2, hereinafter Levaughn) in view of Cunningham et al. (6,306,104 B1, hereinafter Cunningham).

37. Levaughn discloses the claimed invention as set forth and cited above except for expressly disclosing

- for claim 13, a body fluid sampling system, further comprising a penetrating member sensor positioned to monitor a penetrating member coupled to said penetrating member driver, the penetrating member sensor configured to provide information relative to a depth of penetration of a penetrating member through a skin surface;
- for claim 14, a body fluid sampling system, wherein the depth of penetration is about 100 to 2500 microns;

- for claim 15, a body fluid sampling system, wherein the depth of penetration is 500 to 750 microns;
- for claim 16, a body fluid sampling system, wherein the depth of penetration is no more than about 1000 microns beyond a stratum corneum thickness of a skin surface;
- for claim 17, a body fluid sampling system, wherein the depth of penetration is no more than about 500 microns beyond a stratum corneum thickness of a skin surface;
- for claim 24, a body fluid sampling system, wherein a processor is utilized to monitor position and speed of a penetrating member as the penetrating member moves in a first direction; and
- for claim 27, a body fluid sampling system, wherein a processor is utilized to monitor position and speed of a penetrating member as the penetrating member moves in the first direction toward a target tissue, wherein the application of a launching force to the penetrating member is controlled based on position and speed of the penetrating member.

38. Cunningham teaches a body fluid sampling system, comprising *inter alia*:

- for claim 13, a body fluid sampling system, further comprising a penetrating member sensor (column 13 lines 33-64) positioned to monitor a penetrating member coupled to said penetrating member driver (38) (column 9 lines 42-44), the penetrating member sensor configured to provide information relative to a depth of penetration of a penetrating member through a skin surface (column 13 lines 33-64);

- for claim 14, a body fluid sampling system, wherein the depth of penetration is about 100 to 2500 microns (column 9 lines 29-44);
- for claim 15, a body fluid sampling system, wherein the depth of penetration is 500 to 750 microns (column 9 lines 29-44);
- for claim 16, a body fluid sampling system, wherein the depth of penetration is capable of being no more than about 1000 microns beyond a stratum corneum thickness of a skin surface (column 9 lines 29-44);
- for claim 17, a body fluid sampling system, wherein the depth of penetration is capable of being no more than about 500 microns beyond a stratum corneum thickness of a skin surface (column 9 lines 29-44);
- for claim 24, a body fluid sampling system, wherein a processor (column 13 lines 33-34) is capable of monitoring position and speed of a penetrating member as the penetrating member moves in a first direction (column 13 lines 33-34); and
- for claim 27, a body fluid sampling system, wherein a processor (column 13 lines 33-34) is capable of monitoring position and speed of a penetrating member as the penetrating member moves in the first direction toward a target tissue (column 13 lines 33-34), wherein the application of a launching force to the penetrating member is capable of being controlled based on position and speed of the penetrating member (column 13 lines 33-34).

39. All the claimed body fluid sampling system elements were known in the prior art and one skilled in the art could have combined the body fluid sampling system elements as claimed by known methods with no change in their respective functions, and the

combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the body fluid sampling system component parts are known in Levaughn and Cunningham. The only difference is the combination of the body fluid sampling system component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the body fluid sampling system components as taught by Levaughn with the body fluid sampling system components as taught by Cunningham to achieve the predictable results of monitoring and controlling a penetration depth, position and speed of a lancet in order to decrease perceived pain by the lancing subject.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736